

REMARKS

A new paragraph providing a cross reference to related applications has been added to the specification. Claims 8, 9, 11, 19, 20, 23, 24, 27, 28, 34-37, 45, 46, 48-50, 57-60, 69, 71, 74-76, 81, 88, 89, 93 and 97 have been cancelled and new claims 101-103 have been added. Claims 16, 17, 22, 26, 42-44, 61, 65, 68, 70, 72, 82, 90, 94, 98 and 100 have been amended. With this amendment, claims 1-7, 10, 12-18, 21, 22, 25, 26, 29-33, 38-44, 47, 51-56, 61-68, 70, 72, 73, 77-80, 82-87, 90-92, 94-96, and 98-103 are pending. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made."

Respectfully submitted,

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Version With Markings To Show Changes Made

IN THE SPECIFICATION:

A new paragraph captioned "CROSS-REFERENCE TO RELATED APPLICATIONS" has been added on page 1, immediately after the title.

IN THE CLAIMS:

Claims 8, 9, 11, 19, 20, 23, 24, 27, 28, 34-37, 45, 46, 48-50, 57-60, 69, 71, 74-76, 81, 88, 89, 93 and 97 have been cancelled.

Claims 16, 17, 22, 26, 42-44, 61, 65, 68, 70, 72, 82, 90, 94, 98 and 100 have been amended as follows.

- 16. (Amended) The method of claim [13 or] <u>14</u> wherein the protein denaturant is selected from the group consisting of guanidine hydrochloride, detergents, and urea.
- 17. (Amended) The method of claim [13 or] <u>14</u> wherein the protein denaturant is urea.
- 22. (Amended) The method of claim [13 or] <u>14</u> wherein the dilution of the purified protein occurs in about 1 minute or less.
- 26. (Amended) An adjuvant composition comprising at least one purified recombinant invasin protein of claim 1, wherein administration of the adjuvant composition to an animal in combination with an antigen elicts an immune response to the antigen.
- 42. (Amended) An adjuvant composition comprising a purified recombinant invasin protein of [at least 95% purity] claim 1 and having adjuvant activity, the invasin protein comprising an amino acid sequence derived from a protein of a



member of the Shigella or Salmonella genus, or from an enteroinvasive E. coli wherein administration of the adjuvant composition in combination with an antigen to an animal results in production by Th2 cells of at least one cytokine selected from the group consisting of IL-4, IL-5, IL-6, IL-10 and IL-13.

- 43. (Amended) An adjuvant composition comprising a purified recombinant invasin protein of [at least 95% purity] claim 1 and having adjuvant activity, the invasin protein comprising an amino acid sequence derived from a protein of a member of the Shigella or Salmonella genus, or from an enteroinvasive E. coli wherein administration of the adjuvant composition in combination with an antigen to an animal results in production of at least one class of immunoglobulin selected from the group consisting of IgG, IgE, IgM and IgA.
 - 44. (Amended) A vaccine preparation comprising,
- a purified recombinant invasin protein of claim 1 having adjuvant activity,
 - at least one antigen, and
 - a pharmaceutically acceptable carrier, diluent or excipient.
- 61. (Amended) The vaccine preparation of claim [59] $\underline{44}$, wherein the immune response is characterized by the production of at least one cytokine by Th2 cells.
 - 65. (Amended) A vaccine preparation comprising,
- a purified recombinant invasin protein of [at least about 95% purity] <u>claim 1</u> and having adjuvant activity, the invasin protein comprising an amino acid sequence derived from a protein of a member of the *Shigella* or *Salmonella* genus, or from an enteroinvasive *E. coli*,
 - at least one antigen, and
 - a pharmaceutically acceptable carrier, diluent or excipient.



- 68. (Amended) A vaccine preparation for conferring immunity against an organism expressing invasin protein antigens comprising, a purified recombinant invasin protein of claim 1 having adjuvant activity derived from the invasin protein antigens expressing organism against which immunity is desired.
- 70. (Amended) A method for elicting an immune response in an animal comprising, administering to an animal an immune response elicting amount of an adjuvant composition comprising a purified recombinant invasin protein of claim 1.
- 72. (Amended) [t] The method of claim 70 wherein the purified recombinant invasin protein has a purity of at least about 97%.
- 82. (Amended) The method of claim [81] <u>70</u> wherein the class of immunoglobulin is chosen from the group consisting of IqG, IqE, IgM and IgA.
- 90. (Amended) A method for stimulating the production of at least one cytokine by Th2 cells comprising, administering a cytokine production stimulating amount of a purified recombinant invasin protein of [at least about 95% purity] claim 1 comprising an amino acid sequence derived from a protein of a member of the Shigella or Salmonella genus, or from an enteroinvasive E. coli, wherein the cytokine produced is chosen from the group consisting of IL-4, IL-5, IL-6, IL-10 and IL-13.
- 94. (Amended) A method for stimulating production of at least one class of immunoglobulin comprising administration of an immunoglobulin production stimulating amount of a purified recombinant invasin protein of [at least 95% purity] claim 1 comprising an amino acid sequence derived from a protein of a member of the Shigella or Salmonella genus, or from an enteroinvasive E. coli, wherein the class or subclass of

immunoglobulin produced is chosen from the group consisting of IgG, IgE, IgM and IgA.

- 98. (Amended) A method for the delivery of pharmacologically active substances, therapeutic substances, cytotoxic substances, or diagnostic substances into cells comprising administering a pharmacologically active substance, cytotoxic substance, or diagnostic substance and a purified recombinant invasin protein of claim 1.
- 100. (Amended) A method for the delivery of pharmacologically active substances, therapeutic substances, cytotoxic substances, or diagnostic substances to cells comprising a fused protein comprising a recombinant invasin protein of claim 1 and a pharmacologically active substance, therapeutic substance, cytotoxic substance, or diagnostic substance.

New claims 101-103 have been added.